UNPA
UNITED NATURAL PRODUCTS ALLIANCE

May 24, 2012

The Honorable Orrin G. Hatch
United States Senate
Washington, D.C. 20510

RE: S. 3187 – FDA User Fee Reauthorization Bill Amendments
Durbin Amendment #2127 (Dietary Supplement Registration)
Paul Amendment #2143 (Dietary Supplement Claims)

Dear Senator Hatch:

On behalf of the United Natural Products Alliance, based in Salt Lake City, I would like to convey our opposition to the above amendments that Senators Richard Durbin and Rand Paul will offer to the pending Food and Drug Administration Safety and Innovation Act, S. 3187.

UNPA opposes the Durbin amendment for the following reasons. First, it would create significant paperwork filing requirements, thus adding cost and burden to industry without a well-understood associated benefit. And, it would appear to be an unfunded mandate, in that FDA would lack resources to use such a registration database in any useful way.

Further, the NIH Office of Dietary Supplements has commissioned and is currently supporting the development of a National Dietary Supplement Label Database that would capture essentially all of the same information of interest to Senator Durbin as described in his amendment, thus obviating the need for a redundant effort. Of significant concern is that this amendment appears to extend to dietary supplement manufacturers worldwide. It would be extremely difficult to communicate to a global marketplace this requirement, thus resulting in the likelihood of many technical violations (such as "failure to file a notification") that, if enforced by FDA, would cause significant disruption in normal business operations but where no public health or safety issue is involved.

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Finally, Senator Durbin has expressed concerns about sports and energy drinks specifically as a primary reason for this amendment. A great many sport and energy drinks are labeled as conventional foods, not dietary supplements. Thus, should all conventional foods likewise be subject to this registration requirement? We think this inadvisable, given the cost burdens this would impose without any clear benefit.

With regard to the measure to be offered by Senator Rand Paul, UNPA opposes this amendment in that it would effectively overturn the balance contained in a key provision of the Dietary Supplement Health and Education Act (Section 6 Statements of Nutritional Support, or "Structure/Function Claims") by allowing marketing of products with a wide range of claims that would otherwise be regarded as prescription drug, over-the-counter drug, and/or health claims. This amendment would establish a mechanism whereby all such claims could be promoted to consumers without any underlying basis for substantiation of these claims, thus eroding consumer confidence in the current DSHEA regulatory system for product claims. It also contains other more technical amendments to the Federal Food, Drug and Cosmetic Act that could hinder legitimate FDA efforts to remove counterfeit or other illegal products from the market.

While we support broad consumer access to information and claims on dietary supplement labels and labeling, we do not believe this amendment, as drafted, would serve consumer interests. Rather, it is likely to confuse consumers and erode industry investments in substantiation and product research as laid out by DSHEA.

Sincerely,

Loren Israelsen
Executive Director

/hhc

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